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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,671

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Takashi Nakamura

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EXAMINER

SCHILLINGER, ANN M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,671	Applicant(s) NAKAMURA ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Kokubo (United States Patent Number 5,609,633). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

Regarding Claims 1, 2, 3, 7, 8, 9, and 11: Kawatani et al. teaches a porous rough film/body comprising a lump of titanium or titanium alloy (para. 13) and having a porosity of 40-60% (Fig. 1). The body has a larger pore interconnected in a three-dimensional network with a diameter of 100 to 200 micrometers and smaller holes with diameters of 50 microns or (para. 0003). The porous network penetrates the rough film/body from one end to the other. Considering the varied diameters of the pores in Kawatani et al., it is highly probable, if not inherent, that the claimed structure (a smaller hole on an inner surface of the larger interconnected pore) would be formed. The range of the pores taught by Kawatani et al. (100-200 micrometers) anticipates the range in claim 11 (MPEP 2131.03 II). However, Kawatani et al. does not teach the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane.

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Kokubo teaches the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane (2:4-13 and Table 1). Kokubo also teaches that the desirable thickness of the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane is 0.1 to 10 micrometers (2:25-26). This film is made by immersing the titanium in an alkaline aqueous solution followed by a heat treatment (2:30-35). The heat treatment temperature is anywhere from 300 to 800 degrees C (2:40-45). The implant is washed in distilled water after the immersion and before the heat treatment (4:20-25). Kawatani et al. and Kokubo are combinable because they are from the same field of endeavor, namely, bone implants. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified the porous endosseous implant of Kawatani et al. with the osteoinductive film/layer taught by Kokubo, and one would have been motivated to do so because Kokubo suggests that a substrate covered by a film including a phase of alkali titanate would induce the growth of apatite thereon (3:18-24), thus increasing the ability to bond with the bones of the body (1:15-19).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Kokubo (United States Patent Number 5,609,633) as applied to claim 3 above, and further in view of Johnson et al. (United States Patent Application Number 2001/0053937). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

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Regarding Claims 4-6: Kawatani et al. teaches the plasma sprayed body/rough film as applied above. The body is formed by plasma spraying small, irregular titanium particles to a base material/plate (para. 0009). The substrate/base material taught by Kawatani et al. could be considered a “plate”. Furthermore, the titanium powder of Kawatani et al. comprises a group of irregular particles and each of the particles is porous. The porous particles are irregular by nature, considering that: 1. the particles are of varying sizes and 2. the voids are not identical in every particle. Finally, the titanium powder comprises a fine powder having a particle diameter having a particle diameter of 20-30 microns and a coarse/titanium sponge powder having a particle diameter of 100-300 microns (para. 13) (See MPEP 2131.03 and 2144.05). However, Kawatani et al. does not specifically teach a method of shaping this article.

The action of cutting the plasma sprayed metal after it has been plasma sprayed does not merit patentability because it common in the art to cut porous metal materials in order to shape them for implantation. For example, Johnson et al. teaches a porous titanium (para. 0032) bone substitute material that can be shaped by machining/cutting (para. 0048). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the plasma sprayed body taught by Kawatani et al. by the shaping/machining/cutting process taught by Johnson et al., and one would have been motivated to do so in order to be sure that the implant would fit the orthopedic region in question.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Larsson et al. (United States Patent Number 6,689,170). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

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Kawatani et al. teaches a porous rough film/body comprising a lump of titanium or titanium alloy (para. 13) and having a porosity of 40-60% (Fig. 1). The body has a larger pore set interconnected in a three-dimensional network with a diameter of 100 to 200 micrometers and smaller holes with diameters of 50 microns or less (para. 0003). The porous network penetrates the rough film/body from one end to the other. Considering the varied diameters of the pores in Kawatani et al., it is inevitable that the claimed structure (a smaller hole on an inner surface of the larger interconnected pore) would appear. However, Kawatani et al. does not anodizing the body in an electrolytic solution.

Larrson et al. teaches an implant for permanent anchorage in bone tissue which is made of titanium with a titanium oxide surface which has been modified by anodization (Abstract). Kawatani et al. and Larrson et al. are combinable because they are from the same field of endeavor, namely, bone implants. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have combined the method of anodizing the body/implant in an electrolytic solution taught by Larrson et al. with the porous body/implant component taught by KAWATANI ET AL., and one would be motivated to do so because anodization increases the oxide thickness on the titanium surface, and titanium oxide is suspected to increase the biocompatibility of titanium due to the polarity of its surface. The polarity attracts calcium ions and helps incorporate calcium into the surface (2:18-19, 3:36-40, 7:25-28, 10:4-6).

Response to Arguments

Applicant's arguments filed 10/27/2008 have been fully considered but they are not persuasive. The pores of Kawatani et al. do not penetrate the base material, however, this was not a limitation of the original instant claim. The broadest reasonable interpretation of the claim

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does not require that the pores on the outer surface of the implant would penetrate its entire volume, and thus the "rough film" taught by Kawatani et al. could in itself be considered a "porous body."

In the originally filed disclosure, the Applicant states "it has been known that specific ceramic porous bodies comprising hydroxyl apatite etc. has osteoinductivity, which can induce bone formation even in a location which a bone does not intrinsically exist" (page 2, lines 4-10). The Examiner holds that the combination (the film taught by Kokubo on the porous body taught by Kawatani et al.) would inherently be osteoinductive due to the layer of apatite. Paired with the porous body taught by Kawatani et al., the combination appears to have the necessary properties (porosity and a layer of apatite) to induce bone formation anywhere in the body and thus be "osteoinductive".

The osteoinductivity would be an inherent result of coating the pores in apatite. In addition the osteoinductive artificial bone limitation is stated in the preamble of the independent claim. It has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause.

Regarding the film, Kawatani is silent as to whether or not it would have smaller "holes" on its inner surface. Since, Kawatani's porous network penetrates the rough film/body from one end to the other, and it has varied pore diameters, it is probable if not inherent that the claimed structure (a smaller hole on an inner surface of the larger interconnected pore) would be formed. Kawatani et al. explains that the plasma spray process (spraying tiny, variously sized titanium particles) creates pores of various sizes. Some of these sizes are less than 50 micrometers, while

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others are larger (100-200 micrometers) (Kawatani et al. translation, para. 0003). Since all of these variously sized pores are connected, at some point a smaller pore (hole) will intersect a larger one (pore), thus creating a (smaller) hole on the inner surface of the (larger) pore.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774